



UPMC HEALTH SYSTEM

200 Lothrop Street
Pittsburgh, PA 15213-2582

March 5, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Medical Devices: Guidance on Labeling of Reprocessed Single Use Devices
Docket # 01D-0514

Dear Sirs;

On behalf of UPMC Health System we welcome the opportunity to submit comments to the Food and Drug Administration (FDA) concerning Labeling of Reprocessed Single Use Devices (SUD), as published in the Federal Register on December 20, 2001. (Volume 66, Number 245).

We agree with the FDA's position that the original equipment manufacturer's (OEM) name and trademark should not be removed from a reprocessed device. Instead, the additional address and contact of the remanufacturer should be added to the label. This would aid the hospitals and other product users to contact the manufacturer and/or the remanufacturer and the FDA when there is information that reasonably suggests the device may have caused or contributed to the death ...or serious injury of a patient.

We hope these comments will be considered before any final guidelines are released and appreciate the opportunity to submit this response. If you have questions concerning these comments, please feel free to call me at (412) 647-1560.

Sincerely,

Cherie Ivory
Director, Contracting and Regulatory
Review

Cc: K. Hartley
L. Painter
P. Stimmel

01D-0514

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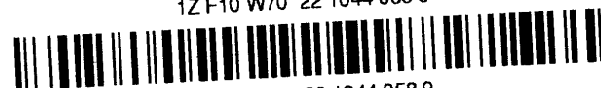
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Eugene Swift – A 1996 Olympian representing the United States in the 110-meter hurdles, Swift is training in the same event for the 2000 Olympic Games in